

Remarks

Reconsideration of the present application is respectfully requested.

I. Status of the Claims

Claims 45-47, 50, 52, 53, 58, 59, 62, 64 and 65 have been amended. Claims 70 and 71 have been added. Claims 45-71 are pending in the present application.

II. Support for the Amendment

Support for the temperature ranges recited in claims 45-47, 58 and 59 is found in the specification, for example, at page 2, next to last paragraph, and page 8, last five lines.

Support for the amendment of claims 50 and 62 is found in the specification at page 10, first paragraph.

Support for the amendment of claims 52, 53, 64 and 65 is found in the specification at page 10, last two paragraphs.

Support for new claims 70 and 71 is found in the specification, for example, at page 2, next to last paragraph, and page 8, last five lines.

No new matter has been added by this amendment.

III. The Inventor Declaration

At page 2 of the Office Action, the Examiner objected to the inventor declaration. Applicants respectfully request that the Examiner hold this objection in abeyance until the remaining issues outstanding in this application are resolved.

IV. The Rejection For Obviousness-Type Double Patenting

At page 3 of the Office Action, the Examiner rejected claims 45-69, for alleged obviousness-type double patenting, over claims 1-10 and 13-16 of U.S. Patent No. 5,891,692 ("the '692 patent") Claims 45-47, 50, 52, 53, 58, 59, 62, 64 and 65 have been amended to overcome various other rejections. As amended, the pending claims are patentably distinct from claims 1-10 and 13-16 of the '692 patent.

As amended, claim 45 recites a method for enhancing the transformation ability and the viability of a bacterium, the method comprising increasing the fatty acid content of the membrane of the bacterium, wherein the bacterium, after increasing its fatty acid content, exhibits an enhanced transformation ability and enhanced viability after storage at a temperature of from about +4°C to about -80°C, relative to the transformation ability and viability exhibited by the bacterium prior to increasing its fatty acid content.

As amended, claim 46 recites a method for enhancing the transformation ability and the viability of bacteria, the method comprising increasing the fatty acid content of the membrane of the bacteria, wherein the bacteria, after increasing their fatty acid content, exhibit an enhanced transformation ability and enhanced viability after storage at a temperature of from about +4°C to about -80°C, relative to the transformation ability and viability exhibited by the bacteria prior to increasing their fatty acid content.

As amended, claim 58 recites a method for enhancing the transformation ability of a bacterium, the method comprising increasing the fatty acid content of the membrane of the bacterium, wherein the bacterium, after increasing its fatty acid content, exhibits an enhanced transformation ability after storage at a temperature of from about +4°C to about -20°C, relative to the transformation ability exhibited by the bacterium prior to increasing its fatty acid content.

As amended, claim 59 recites a method for enhancing the transformation ability of bacteria, the method comprising increasing the fatty acid content of the membrane of the bacteria, wherein the bacteria, after increasing their fatty acid content, exhibit an enhanced transformation ability after storage at a temperature of from about +4°C to about -20°C, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content.

Claims 45-71 in the present application are patentably distinct from claims 1-10 and 13-16 in the '692 patent. The claims in the '692 patent are directed to methods for either enhancing viability (claims 1, 3-10, 13 and 14 of the '692 patent) or transformation ability (claims 2, 3-10, 14 and 16 of the '692 patent). In contrast to the claims in the '692 patent, claims 45-57 and 70 in the present application provide methods for enhancing both transformation ability *and* viability. Thus, claims 45-57 and 70 in the present application are patentably distinct from claims 1-10 and 13-16 in the '692 patent.

In contrast to claims 1-10 and 13-16 in the '692 patent, claims 58-79 and 71 in the present application provide methods for enhancing transformation ability such that, after storage at a temperature of from about +4°C to about -20°C, the bacteria exhibit an enhanced transformation ability. Thus, claims 58-69 and 71 in the present application are patentably distinct from claims 1-10 and 13-16 in the '692 patent.

It is believed that the alleged ground for this obviousness-type double patenting rejection of claims 45-69 is moot. Accordingly, Applicants respectfully request that this rejection be withdrawn.

V. The Rejections Under 35 U.S.C. § 102(b) Must Be Withdrawn

A. The Rejection Over Inoue Must Be Withdrawn

At page 4 of the Office Action, the Examiner rejected claims 45-49 and 51-56, under 35 U.S.C. § 102(b), as allegedly anticipated by Inoue *et al.*, *Gene* 96: 23 (1990) ("Inoue"). The Examiner has relied on the following documents to support this rejection: Ulrich *et al.*, *J. Bact.* 154:221 (1983) ("Ulrich"); de Mendoza *et al.* *Biol. Chem.* 258: 2098 (1983) ("de Mendoza I"); de Mendoza *et al.*, *TIBS* 8: 49 (1983) ("de Mendoza II"); and van Alphen *et al.*, *Eur. J. Biochem.* 101: 571 (1979) ("van Alphen"). Applicants respectfully traverse this rejection.

The amendments of claims 45 and 46 are discussed above. Inoue teaches freezing competent bacteria at -70°C in liquid nitrogen. Inoue fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -80°C, the bacteria exhibit both an enhanced transformation ability and enhanced viability, relative to the transformation ability and viability exhibited by the bacteria prior to increasing their fatty acid content. Therefore, Inoue fails to teach the invention of claims 45-49 and 51-56.

Likewise, Ulrich, de Mendoza I, de Mendoza II and van Alphen each fail to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -80°C, the bacteria exhibit both an enhanced transformation ability and enhanced viability, relative to the transformation ability and viability exhibited by the bacteria prior to increasing their fatty acid content. Therefore, Ulrich, de Mendoza I, de Mendoza II and van Alphen fail to support the rejection of claims 45-49 and 51-56 over Inoue.

Applicants respectfully request that this rejection be withdrawn.

B. *The Rejection Over de Mendoza II Must Be Withdrawn*

At page 5 of the Office Action, the Examiner rejected claims 58-69, under 35 U.S.C. § 102(b), as allegedly anticipated by de Mendoza II. Applicants respectfully traverse this rejection.

The amendments of claims 58 and 59 are discussed above. de Mendoza II fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -20°C, the bacteria exhibit an enhanced transformation ability, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content. Therefore, de Mendoza II fails to teach the invention of claims 58-69. Applicants respectfully request that this rejection be withdrawn.

C. *The Rejection Over Emtseva Must Be Withdrawn*

At page 6 of the Office Action, the Examiner rejected claims 58-63 and 66, under 35 U.S.C. § 102(b), as allegedly anticipated by Emtseva ("Emtseva"). Applicants respectfully traverse this rejection.

The amendments of claims 58 and 59 are discussed above. Emtseva fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -20°C, the bacteria exhibit an enhanced transformation ability, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content. At best, Emtseva provides that after growing a *Serratia marcescens* strain and an *Erwinia aroideae* strain in a culture broth containing 0.2% oleic acid, cell viability was increased after lyophilization and storage at -70°C. Emtseva is silent concerning transformation ability, and fails to teach that any property is enhanced in cells stored at -20°C or above. Therefore, Emtseva fails to teach the invention of claims 58-63 and 66. Applicants respectfully request that this rejection be withdrawn.

D. The Rejection Over Tsien Must Be Withdrawn

At page 7 of the Office Action, the Examiner rejected claims 58-61 and 66-68, under 35 U.S.C. § 102(b), as allegedly anticipated by Tsien *et al.*, *J. Gen. Microbiol.* 121: 105 (1980) ("Tsien"). Applicants respectfully traverse this rejection.

The amendments of claims 58 and 59 are discussed above. Tsien fails to teach storage of cells at a temperature of from about +4°C to about -20°C. Further, Tsien fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -20°C, the bacteria exhibit an enhanced transformation ability, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content. Therefore, Tsien fails to teach the invention of claims 58-61 and 66-68. Applicants respectfully request that this rejection be withdrawn.

E. The Rejection Over Kole Must Be Withdrawn

At page 7 of the Office Action, the Examiner rejected claims 58-61 and 66-68, under 35 U.S.C. § 102(b), as allegedly anticipated by Kole *et al.*, *Appl. Environ. Microbiol.* 47: 1150 (1984) ("Kole"). Applicants respectfully traverse this rejection.

The amendments of claims 58 and 59 are discussed above. Kole fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about +4°C to about -20°C, the bacteria exhibit an enhanced transformation ability, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content. At best, Kole teaches that a bovine bile resistant *Leuconostoc oenos* strain displayed increased viability after lyophilization, and *before* storage at -20°C. See Kole at page 1151, first paragraph. Thus, Kole

teaches that to the extent that an increase in viability was observed, such an increase in viability was observed *before* storage at -20°C . Kole is silent concerning the viability of bacteria *after* storage at -20°C .

Further, since Kole is silent concerning transformation ability, Kole fails to teach that transformation ability remains enhanced in cells after storage. Therefore, Kole fails to teach the invention of claims 58-61 and 66-68. Applicants respectfully request that this rejection be withdrawn.

VI. The Rejection Under 35 U.S.C. § 103 Must Be Withdrawn

At page 9 of the Office Action, the Examiner rejected claims 64-67, under 35 U.S.C. § 103, as allegedly obvious over Emtseva in view of either de Mendoza I or van Alphen. Applicants respectfully traverse this rejection.

Claims 64-67 depend, either directly or indirectly, from claim 59. Emtseva fails to teach that after increasing the fatty acid content of bacteria and after storage of the bacteria at a temperature of from about $+4^{\circ}\text{C}$ to about -20°C , the bacteria exhibit an enhanced transformation ability, relative to the transformation ability exhibited by the bacteria prior to increasing their fatty acid content. At best, Emtseva purports to show that after growing a *Serratia marcescens* strain and an *Erwinia aroideae* strain in a culture broth containing 0.2% oleic acid, cell viability was increased after lyophilization and storage at -70°C , not at a temperature of from about $+4^{\circ}\text{C}$ to about -20°C . Since Emtseva is silent concerning transformation ability, Emtseva fails to suggest that bacteria in which the fatty acid content had been increased would have exhibited increased transformation ability after storage at a temperature of from about $+4^{\circ}\text{C}$ to about -20°C .

Neither de Mendoza I nor van Alphen cure the deficiency of Emtseva, because both de Mendoza I and van Alphen are silent concerning storage of cells after increasing the fatty acid content. Further, neither de Mendoza I nor van Alphen suggest that bacteria in which the fatty acid content had been increased would have exhibited an increased transformation ability after storage at a temperature of from about +4°C to about -20°C.

Further, one of ordinary skill in the art would not have been motivated to combine the teachings of Emtseva and de Mendoza I or van Alphen, because the 50 degree difference in temperature between -70°C (taught by Emtseva) and -20°C (as claimed) is too great for one of ordinary skill in the art to have imagined that after storage at -20°C or above, the bacteria would have exhibited an enhanced transformation ability.

Even if the teachings of Emtseva and de Mendoza I or van Alphen fail were combined, which cannot properly be done, they would have failed to suggest the invention of claims 64-67. At best, the combined teachings of Emtseva and de Mendoza I or van Alphen would have provided bacteria that exhibit increased viability after storage at -70°C, but not an increase in transformation ability after storage at a temperature of from about +4°C to about -20°C.

Further, even in combination, Emtseva and either de Mendoza I or van Alphen would have failed to provide a reasonable expectation of obtaining bacteria in which, after increasing the fatty acid content, the bacteria would have exhibited an increase in transformation ability after storage at a temperature of from about +4°C to about -20°C, relative to the transformation ability exhibited by cells prior to increasing the fatty acid content. The 50 degree difference in temperature between -70°C and -20°C is too great for one of ordinary skill in the art to have imagined that after storage at -20°C or above, the cells would have exhibited an enhanced transformation ability.

For the above reasons, Emtseva and either de Mendoza I or van Alphen fail to suggest the claimed invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

VII. The Rejection Under 35 U.S.C. § 112, First Paragraph, Must Be Withdrawn

At page 10 of the Office Action, the Examiner rejected claims 45-69 as allegedly not enabled. Applicants respectfully traverse this rejection.

A. The Standard for Enablement

The initial burden of proving that a specification is non-enabling is on the Examiner. Under controlling Federal Circuit case law, it is axiomatic that a specification is presumed to be enabling unless the Examiner provides acceptable objective evidence or sound scientific reasoning showing that it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. In *In re Cortright*, 165 F.3d 1353, 49 USPQ2d 1464, 1469 (Fed. Cir. 1999), the court stated that the PTO cannot make a 112, first paragraph, rejection for lack of enablement, unless the PTO "has reason to doubt the objective truth of the statements contained in the written description." The *Cortright* panel cited *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). In *Marzocchi*, the court stated:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

169 USPQ 367, 369 (CCPA 1971).

Thus, under *Cortright* and *Marzocchi*, the claims in an application are presumed to be enabled, unless proven otherwise. Further, it is well-established that some experimentation is permitted, so long as it is not "undue." See *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation.") (citations omitted); see also *Ex parte Forman*, 230 USPQ2d 546, 547 (BPAI 1986) ("The ultimate question . . . is whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the relevant field to practice the invention claimed therein with out the exercise of undue experimentation.").

At page 10 of the Office action, the Examiner rejected claims 45-69. At pages 12-13 of the Office Action, the Examiner rejected claims 50 and 62 separately from the rejection of claims 45-69. Each rejection is discussed below.

B. The Rejection of Claims 45-69 Must Be Withdrawn

1. A Prima Facie Case of Non-Enablement Has Not Been Established

In the Office Action mailed April 12, 1999 (Paper No. 2), the Examiner rejected then pending claims 1-44 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In the reply filed July 12, 1999, Applicants argued that a *prima facie* case of non-enablement had not been established, because neither objective evidence nor sound scientific reasoning had been presented to doubt that the claimed invention was enabled.

At pages 10-13 of the Office Action mailed September 22, 1999 ("the Office Action"), the Examiner proffered reasons that claims 45-69 are allegedly not enabled. However, the proffered reasons fail to establish a *prima facie* case of non-enablement, because, again, neither objective

evidence nor sound scientific reasoning has been presented to show that the claimed invention is not enabled. In view of Applicants' application and knowledge possessed by one of ordinary skill in the art, the claimed invention is enabled.

a. The Nature of the Invention

With respect to the nature of the invention, claims 45 and 46 provide a method for enhancing the transformation ability and the viability of bacteria, wherein after storage at a temperature from about +4°C to about -80°C, bacteria exhibit an enhanced transformation ability and enhanced viability. Claims 58 and 59 provide a method for enhancing the transformation ability bacteria, wherein after storage at a temperature from about +4°C to about -20°C, bacteria exhibit an enhanced transformation ability.

b. The State of the Prior Art

With respect to the state of the prior art, at page 11 of the Office Action, the Examiner stated:

The art only recognizes that an increase in unsaturated fatty acids result in enhanced transformation ability and viability. Thus, given the teachings of the prior art it is unpredictable that increases in saturated fatty acids results or total fatty acid content (no change in ratio of unsaturated to saturated fatty acids) will result in the same enhanced transformation ability and viability.

Applicants respectfully disagree. With respect to claims 45-57 and 70, the prior art did *not* recognize that increasing the unsaturated fatty acid content results in both enhanced transformation ability *and* enhanced viability after storage at a temperature from about +4°C to about -80°C. With respect to claims 58-69 and 71, the prior art did *not* recognize that increasing the fatty acid content

results in enhanced transformation ability after storage at a temperature from about +4°C to about -20°C.

For the claimed invention to be enabled, it is not necessary for the prior art to predict the claimed invention. That is, the prior art need not "suggest" the claimed invention in order for the invention to be patentable. Indeed, if it was necessary for the prior art to "suggest" a claimed invention for the invention to be meet the enablement requirement of 35 U.S.C. § 112, first paragraph, then no invention would be patentable under 35 U.S.C. § 103!

Neither controlling Federal Circuit case law nor the MPEP require that the prior art somehow "predict" a claimed invention. Instead, when examining claims for compliance with the enablement requirement, the state of the art is to be considered in order to determine whether, based on the disclosure in the specification, undue experimentation would have been required to make and used a claimed invention.

c. Guidance Provided By The Specification

With respect to the amount of direction or guidance provided by the present specification, at page 11 of the Office Action, the Examiner stated:

Applicant's disclosure does not demonstrate (or teach) that enhanced transformation ability and viability of bacteria is achieved with an increase in total fatty acid content (no change in the ration [sic] of unsaturated to saturated fatty acids) or with an increase in saturated fatty acids in the bacterial membranes. Applicant's disclosure is drawn to the increase in the proportion of unsaturated fatty acids in the membrane.

For the claimed invention to be patentable, it is not necessary that every embodiment encompassed by the claims be demonstrated in the specification. While the presence or absence of working examples is one of several factors to be considered in determining enablement, working

examples are not *required* in order for a claimed invention to be enabled. *In re Robins*, 166 USPQ 552, 555 (CCPA 1970) (“[R]epresentative examples are not required by the statute and are not an end in themselves. Rather, they are a *means* by which certain requirements of the statute may be satisfied.”). *See also* MPEP § 2164.02 (“Compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn on whether an example is disclosed.”)

Therefore, simply because not every embodiment encompassed by the claims is exemplified in a working example, the present specification, that does not mean that the claimed invention is not enabled. When the claimed invention is considered in light of the present specification and the knowledge possessed by those of ordinary skill in the art, it is clear that the claimed invention is enabled.

d. The Breadth Of The Claims

At pages 11-12 of the Office Action, the Examiner explained that the claims are broad. Independent claims 45, 46, 58 and 59 are broader than the claims that depend, respectively, from claims 45, 46, 58 and 59. The Examiner has not explained why the fact that some of the claims are broader than others somehow means that the claimed invention is not enabled.

In fact, the Examiner has rejected each of claims 45-69, even though the claims encompass embodiments of varying scope. However, the Examiner has failed to provide acceptable objective evidence or sound scientific reasoning showing that it would require undue experimentation for one of ordinary skill in the art to make and use the invention of each and every claim. Therefore, the Examiner has failed to create a *prima facie* case of non-enablement for each claim. Instead, except for the additional enablement rejection of claims 50 and 62, discussed below, the Examiner has applied a blanket rejection to every claim, and has not considered whether each claim is enabled,

which is improper. See MPEP § 2164.08 ("All questions of enablement are evaluated against the *claimed* subject matter. . . . No claim should be overlooked.") (emphasis added)

e. The Quantity of Experimentation

At page 12 of the Office Action, the Examiner argued that because the specification purportedly fails to provide examples of increasing saturated fatty acid content, the claimed invention is not enabled. The Examiner stated:

In the absence of specific teachings and guidance from the specification, the skilled artisan would resort to empirical experimentation to practice the full scope of the claimed invention with no expectation of success. The skilled artisan would not have an expectation of success because of the teachings of the prior art which clearly demonstrate that the fluidity of bacterial membranes is the result of an increase in the level of unsaturated fatty acids in the membranes and that increased fluidity of the membranes leads to enhanced transformation ability and viability. This level of experimentation with no expectation of success would be undue on the part of the skilled artisan.

Applicants respectfully disagree. That one of ordinary skill in the art may have performed empirical experimentation in order to make and use the claimed invention does *not* render an invention unpatentable for lack of enablement. "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation." *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(citations omitted). "The ultimate question . . . is whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation." *Ex parte Forman*, 230 USPQ2d 546, 547 (BPAI 1986).

Further, simply because an increase in the relative amount of certain unsaturated fatty acids is associated with enhanced transformation ability or enhanced viability does not mean that an increase in the saturated fatty acid content cannot be associated with enhanced transformation ability or enhanced viability. For claims that recite "increasing the fatty acid content" to be enabled, it is not necessary that the prior art teach that an increase in saturated fatty acid content correlates with enhanced transformation ability or enhanced viability. For those claims to be enabled, it is adequate that based on the present specification and the knowledge possessed by one of ordinary skill in the art, one of ordinary skill could have practiced the claimed method without undue experimentation. Here, the Examiner has failed to establish that undue experimentation would have been required.

3. *The Claimed Invention Could Have Been Practiced Without Undue Experimentation*

Contrary to the Examiner's unsupported or inapplicable arguments as to why the present invention is allegedly not enabled, following are reasons why the claimed invention is enabled. Applicants have disclosed at least two specific ways to practice the claimed methods. For example, in Example 1, Applicants discuss that the claimed methods could be practiced by cycling bacteria through an unfavorable condition, such as storage at -20°C, and selecting bacteria having the properties recited in the claims. Further, in the detailed description, and in the examples, Applicants discuss that the claimed methods could also be practiced by transforming bacteria with one or more genes that result in an increase in fatty acid content of the bacterial membrane.

Moreover, the prior art provides evidence that those of ordinary skill in the art knew how to increase the saturated and unsaturated fatty acid content of bacterial membranes. For example, the nucleic acid encoding one or more fatty acid synthesizing enzymes could have been introduced into

bacteria by transduction. *See Microbiology, Fundamentals and Applications*, Atlas, R.M., ed., MacMillan Publishing Company, New York, pp 214-219 (1988), a copy of which is attached.

Alternatively, fatty acid content could have been manipulated by growing bacteria in a growth medium containing an excess of the desired fatty acid(s). For example, *see Emtseva*, which teaches that after growing a *Serratia marcescens* strain and an *Erwinia aroideae* strain in a culture broth containing 0.2% oleic acid was associated with a change in the ratio of saturated fatty acids to unsaturated fatty acids.

Alternatively, fatty acid content could have been manipulated by growing bacteria at temperatures that facilitate unsaturated fatty acid synthesis. For example, *see de Mendoza I*, *de Mendoza II*, *Tsien*, *Ulrich* and *van Alphen*.

Alternatively, fatty acid content could have been manipulated by selecting bacteria that are resistant to bovine bile. For example, *Kole* teaches that bovine bile resistant bacteria exhibited alterations in both saturated and unsaturated fatty acid content. *See Kole* at the abstract, last sentence, and at Table 2, on page 1152.

Thus, given Applicants' disclosure and the knowledge possessed by one of ordinary skill in the art, the claimed invention could have been practiced without undue experimentation. Because no evidence to the contrary has been presented, this rejection is improper. Applicants respectfully request that this rejection be reconsidered and withdrawn.

C. The Rejection Of Claims 50 and 62 Must Be Withdrawn

At pages 12-13 of the Office Action, the Examiner stated that claims 50 and 62 are allegedly not enabled because the specification does not teach how an increase in gene copy number is obtained.

Claims 50 and 62 have been amended to recite "wherein said one or more genes are comprised by one or more vectors."

As a result of the amendment of claims 50 and 62, it is believed that the alleged ground for this rejection is moot. Accordingly, Applicants respectfully request that this rejection be withdrawn.

VIII. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Must Be Withdrawn

A. The Rejection For Alleged Lack Of Method Steps Must Be Withdrawn

At page 13 of the Office Action, the Examiner rejected claims 45-69, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants respectfully traverse this rejection.

At pages 13-14 of the Office Action, the Examiner stated:

Claims 45-69 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amount to a gap between the steps. See MPEP § 2172.01. The method steps do not [sic] recite any method steps which result in increasing the fatty acid content of the membrane of a bacterium, thus the metes and bounds of the claims cannot be established.

With respect to the Examiner's statement about a "gap" between the claims, Applicants respectfully point out that the Examiner has misread the claim. The claims recite, in part, "said method comprising increasing the fatty acid content of the membrane." In the absence of more than one "step," there can be no "gap" between steps.

With respect to the Examiner's statement about reciting steps which result in increasing the fatty acid content, the Examiner apparently wishes for Applicants to recite in the claims the *mechanism* by which fatty acid content is increased. However, neither the MPEP nor controlling Federal Circuit case law requires that a method claim recite *how* a claimed result is obtained. Indeed, the Federal Circuit has explained that it is not even necessary that Applicants *know* how an invention

works. *See In re Cortright*, 49 USPQ2d 1464, 1469 (Fed. Cir. 1999) (“[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.”) (citing *Newman v. Quigg*, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)).

For the foregoing reasons, it is believed that this rejection is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. The Rejection For Alleged Lack Of Clarity Must Be Withdrawn

At page 14 of the Office Action, the Examiner rejected claims 45-69, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, because it is allegedly not clear what “increasing the fatty acid content of the membrane” means. Applicants respectfully traverse this rejection.

Based on the disclosure of the present application, one of ordinary skill in the art would have understood the term “increasing the fatty acid content” to encompass an increase in the total amount of one or more fatty acids, whether saturated or unsaturated. Since the metes and bounds of the claims would have been understood by one of ordinary skill in the art, Applicants respectfully request that this rejection be withdrawn.

IX. The Objections To The Claims Must Be Withdrawn

At page 14 of the Office Action, the Examiner objected to claims 52, 53, 64 and 65. Applicants respectfully traverse these objections.

Claims 52 and 64 have been amended to recite “the genus of *Escherichia*.” Claims 53 and 65 have been amended to recite “the species *Escherichia coli*.” Applicants thank the Examiner for suggesting claim language. Applicants respectfully request that these objections be withdrawn.



F.R. Bloom *et al.*
Appl. No. 09/227,742

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Grant E. Reed
Attorney for Applicants
Registration No. 41,264

Date: 3/21/2000

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005
(202) 371-2600